CURRICULUM VITA - MARCIA S. YAROSS, PH.D.

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EDUCATION

- Ph.D., Cell and Developmental Biology, University of California, Irvine
- B.A., Biology, Reed College, Portland, Oregon

PROFESSIONAL EXPERIENCE

BIOSENSE WEBSTER INC., a Johnson & Johnson company **2002-present**

Vice President, Clinical, Quality & Regulatory Affairs

- Overall global responsibility for clinical research, product quality, and regulatory affairs activities for a leading manufacturer of medical devices for the diagnosis and treatment of cardiac arrhythmias.

ALLERGAN, INC./ADVANCED MEDICAL OPTICS (AMO) **1994-2002**

Director, Worldwide Regulatory Affairs and Medical Compliance

- Overall global responsibility for regulatory activities for AMO unit, spun off as independent company in June, 2002.
- Directed global product registration activities for broad range of ophthalmic surgical and contact lens care products, including implantable devices, sterile solutions, and computerized microsurgical equipment.
- Managed post-market surveillance activities to meet U.S. and international requirements.

MINIMED TECHNOLOGIES, LTD. **1992-1994**

Director, Regulatory Affairs and Clinical Research

- Directed all clinical research and regulatory activities for the diabetes care division, reporting to the President and CEO.
- Conducted international clinical trials for a unique drug/device combination product.
- Directed preparation of PMA, NDA, 510(k) and EC drug/device registration dossiers.

KABI PHARMACIA OPHTHALMICS, INC. **1986-1992**
(Formerly Intermedics Intraocular, Inc. and Pharmacia Ophthalmics, Inc.)

Vice President, Clinical and Regulatory Affairs, 1989-1992

- Responsible for regulatory affairs and clinical research policy and activities within firm.
- Obtained FDA approvals for new products and manufacturing facilities (U.S. and foreign sites).

Negotiated protocols for collaborative studies to meet U.S. and E.C. requirements.

KABI PHARMACIA OPHTHALMICS, INC. (cont.) **1986-1992**
(Formerly Intermedics Intraocular, Inc. and Pharmacia Ophthalmics, Inc.)

Director of Regulatory Affairs, 1989
- Coordinated operations of the Departments of Regulatory Affairs, Clinical Research and Biostatistics, and Quality Assurance and Engineering, supervising total of 50 direct and indirect reports.
- Managed GMP plant inspections by U.S. FDA, State of California and foreign governmental authorities.
- Directed all U.S. clinical research for intraocular lenses.

Manager of Regulatory Affairs, 1987-1988
- Supervised preparation of regulatory submissions.
- Created system for computerized preparation of regulatory documents.
- Generated clinical studies sections of PMAs.

Regulatory Affairs Coordinator, 1986-1987
- Coordinated medical complaint investigations.
- Streamlined adverse reaction and MDR reporting programs.

UNIVERSITY OF CALIFORNIA, IRVINE **---**

Assistant Research Biologist
- Conducted basic research in stem cell biology as Principle Investigator of National Science Foundation grant entitled "Multipotential Cell Differentiation: Cell Cycle Aspects."
- Initiated operation of UCI's flow cytometry research facility.

STANFORD UNIVERSITY SCHOOL OF MEDICINE **---**

Research Associate
- Planned and performed basic research on skeletal muscle development
- Developed new assays for screening monoclonal antibodies to cell surface molecules.

UNIVERSITY OF VIRGINIA **---**

Postdoctoral Research Fellow
- Planned and performed basic research on embryonic limb and muscle development.
- Awarded individual fellowships from the National Institutes of Health and the Muscular Dystrophy Association.

MISCELLANEOUS

- Industry Representative to FDA's Ophthalmic Devices Advisory Panel, 1997-2001.
- Orange County Regulatory Affairs Discussion Group, President, 2001-2002; Board of Directors, 2000-2004.
- Publications - available upon request